ISRCTN17914189 https://doi.org/10.1186/ISRCTN17914189

A trial to learn about the long-term safety and efficacy of a study drug (STAR-0215) in adult patients with hereditary angioedema

Submission date
03/01/2024

Recruitment status
No longer recruiting

Registration date
18/07/2024

Overall study status
Ongoing

Last Edited
27/12/2024

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
STAR-0215-202 is a long-term, open-label trial to assess the safety and efficacy of repeat dosing of STAR-0215 for the prevention of acute attacks in adult patients with Type 1or Type 2 hereditary angioedema (HAE). Participants may either enroll from the Phase 1b/2 STAR 0215 201 (ALPHA-STAR) trial or be STAR-0215 naïve and not enrolled in STAR-0215-201. HAE is a rare genetic disorder that causes repeated and unpredictable attacks of swelling in the face, arms and legs, abdomen, genitals, and airways. The aim of this study is to assess the long-term safety and tolerability of STAR 0215 in participants with Type 1 or Type 2 HAE. STAR-0215 drug product is supplied as a sterile, preservative-free solution for subcutaneous injection. Participants may receive STAR-0215 subcutaneously for up to 5 years, or until marketing authorization, whichever comes first.

Who can participate?
About 56 participants with HAE will take part in the trial globally.

What does the study involve?
All participants will receive STAR-0215 and will be assigned to receive one of three dosing regimens:
Dosing Regimen 1: Day 1 will receive a dose of STAR-0215, then will continue dosing every 3 months
Dosing Regimen 2: Day 1 will receive a dose of STAR-0215, then will continue dosing every 6 months
Dosing Regimen 3: Day 1 will receive a dose of STAR-0215, another dose 1 month later, then will continue dosing every 6 months
The dosing regimen to which they are assigned will depend on the cohort they were in while participating in the STAR-0215-201 trial: If they were in cohorts 1 or 2, they will be in Dosing Regimen 1 and if they were in cohort 3, they will be in Dosing Regimen 2. Participants who never received any dose of STAR-0215 will be assigned to a dosing regimen sequentially in relation to other participants without previous cohort assignment.
Participants will have a total of about 23 study site visits and 4 remote contact visits if in Dosing

Regimen 1, about 17 study site visits and 9 remote contact visits if in Dosing Regimen 2, and about 18 study visits and 9 remote contacts for Dosing Regimen 3. Following the last dose of STAR-0215 they will continue to be monitored to check for any safety concerns, regardless of dosing regimen. This follow-up period consists of 2 study site visits and 4 remote contact visits.

What are the possible benefits and risks of participating?
There may not be a direct medical benefit from receiving the study drug. Participants' HAE may get better, stay the same, or even get worse.
It is possible that the results may not help individuals but the information from this study will help improve treatment for people with HAE in the future.

Where is the study run from?
Astria Therapeutics, Inc. (USA)

When is the study starting and how long is it expected to run for?
May 2023 to March 2031

Who is funding the study?
Astria Therapeutics, Inc. (USA)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number
1009099

ClinicalTrials.gov number
NCT06007677

Secondary identifying numbers
STAR-0215-202, IRAS 1009099, CPMS 59129

Study information

Scientific Title
A Phase II long-term open-label trial to assess the safety and efficacy of repeat dosing of STAR-0215 in adult patients with hereditary angioedema (the ALPHA-SOLAR trial)

Acronym
The ALPHA-SOLAR Trial

Study objectives
1. To assess the long-term safety and tolerability of STAR-0215 in participants with Type 1 or Type 2 hereditary angioedema (HAE)
2. To assess the long-term efficacy of STAR-0215 in participants with Type 1 or Type 2 HAE
3. To characterize the pharmacokinetics (PK) of long-term STAR-0215 dosing in participants with Type 1 or Type 2 HAE
4. To characterize the pharmacodynamics (PD) of long-term STAR-0215 dosing in participants with Type 1 or Type 2 HAE

5. To assess the immunogenicity of STAR-0215 dosed long-term in participants with Type 1 or Type 2 HAE

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/03/2024, East Midlands - Leicester South Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8143; Leicestersouth.rec@hra.nhs.uk), ref: 24/EM/0017

Substantial Amendment 01: Approved 05/09/2024

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice, Hospital, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Hereditary angioedema (HAE)

Interventions
Current interventions as of 18/12/2024:
In this trial, participants will be assigned to one of the following groups:

Dosing Regimen 1:
Day 1 participants will receive a dose of STAR-0215, then will continue dosing of STAR- 0215 every 3 months. The maximum duration that participants will receive the study drug is up to 5 years.

Dosing Regimen 2:
Day 1 participants will receive a dose of STAR-0215, then will continue dosing of STAR- 0215 every 6 months. The maximum duration that participants will receive the study drug is up to 5 years.

Dosing Regimen 3:
Day 1 participants will receive a dose of STAR-0215, and another dose one month later. Then participants will continue dosing of STAR-0215 every 6 months. The maximum duration that participants will receive the study drug is up to 5 years.

Follow-up activity:
Following the last dose of STAR-0215, participants will continue to be monitored to check for any safety concerns. This period will consist of 4 remote contacts and 2 visits at the study site.

Previous interventions:
In this trial, participants will be assigned to one of the following groups:

Dosing regimen 1:
Day 1 participants will receive a loading dose of STAR-0215, then will continue dosing of STAR-0215 every 3 months. The maximum duration that participants will receive the study drug is up to 5 years.

Dosing regimen 2:
Day 1 participants will receive a dose of STAR-0215, and another loading dose one month later. Then participants will continue dosing of STAR-0215 every 6 months. The maximum duration that participants will receive the study drug is up to 5 years.

Follow-up activity:
Following the last dose of STAR-0215, participants will be monitored for 16 months to check for any safety concerns. This period will consist of six remote contacts and two visits to the study site.

Previous interventions:
In this trial, participants will be assigned to one of the following groups:

Dosing regimen 1:
Day 1 participants will receive a loading dose of STAR-0215, then will continue dosing of STAR-0215 every 3 months. The maximum duration that participants will receive the study drug is up to 5 years.

Dosing regimen 2:
Day 1 participants will receive a dose of STAR-0215, and another loading dose one month later. Then participants will continue dosing of STAR-0215 every 6 months. The maximum duration that participants will receive the study drug is up to 5 years.

Follow-up activity:
Following the last dose of STAR-0215, participants will be monitored for 16 months to check for any safety concerns. This period will consist of six remote contacts and two visits to the study site.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)

STAR-0215

Primary outcome measure
Current primary outcome measure as of 18/12/2024:
Number of participants experiencing treatment-emergent adverse events [time frame: day 1 through study completion, an average of 6 years

Previous primary outcome measure:
Number of participants experiencing treatment-emergent adverse events [time frame: day 1 through up to 6 years and 4 months]

Secondary outcome measures
1. Change from baseline in monthly HAE attack rate [time frame: day 1, up to 5 years]
2. Severity of HAE attacks experienced by participants [time frame: day 1 through up to 5 years]. All HAE attacks will be classified according to severity (mild, moderate, and severe).
3. Duration of HAE attacks [time frame: day 1 through up to 5 years]. Duration will be reported as shorter than 12 hours, 12 to 24 hours, 24 to 48 hours, and longer than 48 hours.
4. Number of participants experiencing HAE attacks requiring on-demand therapy [time frame: day 1 through up to 5 years]
5. Time to first HAE attack after each dose [time frame: day 1 through up to 5 years]
6. Number of HAE attack-free days [time frame: day 1 through up to 5 years]
7. Number of participants experiencing zero HAE attacks [time frame: day 1 through up to 5 years]
8. Serum concentration of STAR-0215 [time frame: every 3 months for first 2 years, every 6 months for next 3 years]. Blood samples will be collected on dosing days to measure the serum concentration of STAR-0215.
9. Plasma levels of cleaved high-molecular-weight kininogen [time frame: every 3 months for first 2 years, every 6 months for next 3 years]. Blood samples will be collected on dosing days to measure the plasma levels of cleaved high-molecular-weight kininogen (a measure of plasma kallikrein activity).
10. Number of participants with anti-drug antibodies to STAR-0215 [time frame: every 3 months for first 2 years, every 6 months for next 3 years]. Blood samples will be collected on dosing days to assess the formation of STAR-0215 anti-drug antibodies in serum.

Overall study start date
19/05/2023

Completion date
31/03/2031

Eligibility

Key inclusion criteria
Open to participants from STAR-0215-201 (NCT05695248) who have met one of the following conditions:
1. Completed STAR-0215-201 (follow up through 6 months after their last dose)
2. Eligible for STAR-0215-201 and entered the Run-In period but did not qualify for the Treatment Period because they did not meet the criterion for the minimum number of HAE attacks
3. Eligible for STAR-0215-201 and entered the Run-In period but did not complete it for reasons other than not meeting the criterion for the minimum number of HAE attacks (eligibility requires

consultation with the Medical Monitor)
4. Discontinued STAR-0215-201 (for reasons other than safety) after having completed at least 84 days of trial follow-up since their last dose of STAR-0215 (eligibility requires consultation with the Medical Monitor)

Added 19/11/2024:
Open to participants who are STAR-0215 naïve and were not enrolled in STAR-0215-201 (NCT05695248), and have a documented diagnosis of HAE (Type 1 or Type 2).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
56

Key exclusion criteria
1. Any concomitant diagnosis of another form of chronic angioedema, such as acquired C1 inhibitor deficiency, HAE with normal C1-esterase inhibitor protein (also known as HAE Type III), idiopathic angioedema, or angioedema associated with urticaria.
2. Any exposure to angiotensin-converting enzyme inhibitors or any estrogen-containing medications with systemic absorption (such as hormonal contraceptives or hormone replacement therapy) within 28 days prior to Screening
3. Any exposure to androgens (for example, stanozolol, danazol, oxandrolone, methyltestosterone, testosterone) within 7 days prior to Screening.
4. Use of therapies prescribed for the prevention of HAE attacks prior to Screening:
4.1. Lanadelumab within 90 days
4.2. Berotralstat within 21 days
4.3. All other prophylactic therapies, discuss with the Medical Monitor
Note: Other inclusion and exclusion criteria may apply.

Date of first enrolment
26/09/2023

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
Bulgaria

Canada

Czech Republic

England

Germany

Poland

United Kingdom

United States of America

Study participating centre
St James' University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
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United Kingdom
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Study participating centre
Addenbrookes Hospital
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Astria Therapeutics, Inc.

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication
6. Submission to regulatory authorities

Coded study data will be shared via secure Sponsor systems. Data sharing will be in accordance with current data privacy legislation and restricted to authorized parties with the necessary confidentiality agreements in place.

Intention to publish date
31/03/2032

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date